

K970784

MAY 13 1997

510k Submission for  
**QuikPac II One Step Methamphetamine Test**

Syntron Bioresearch, Inc.

Page 58 of 58 Pages

Revision C 4/11/97 Printed on 4/22/97

---

## **Summary of Safety and Effectiveness**

The sponsor, Syntron Bioresearch, Inc. (2774 Loker Ave. West, Carlsbad, California, 92008), has developed, manufactured and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Methamphetamine and its metabolites in a screening format.

The trade name of the device is **QuikPac II One Step Methamphetamine Test** having a designated common name of **Methamphetamine Test System** and a classification as a class II device per 21 CFR § 862.3610. This device is intended for medical/forensic screening of urine.

Syntron's **QuikPac II One Step Methamphetamine Test** consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody:antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 500 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

In-house testing of Syntron's **QuikPac II One Step Methamphetamine Test** yielded a relative sensitivity and specificity of 1.00 and an accuracy of 100% when tested against Syva EMIT® II on samples documented to be positive by GC/MS. A clinical trial consisting of 305 samples was run and the combined data yielded a relative sensitivity of 100%, a relative specificity of 97.7% with an accuracy of 98.68%.

All positive samples by either screening method were confirmed by GC/MS. The results on the 6 discrepant samples clearly demonstrated the specificity of the **QuikPac II One Step Methamphetamine Test**. Four of the 6 samples were negative for methamphetamine, but positive for Amphetamine by GC/MS. The other two were negative for methamphetamine but positive for pseudoephedrine and phenyl propanolamine (PPA) respectively.

Additional information on this submission may be obtained by contacting Dr. Cleve W. Laird, President, Drial Consultants, Inc. at 805-522-6223(Ca) or by fax at 805-522-1526.